

Assessment Factors for Evaluating the Quality of Information from External Sources

1. Introduction

In the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (“Guidelines”),¹ the Environmental Protection Agency (EPA or the Agency) articulates the Agency’s ongoing commitment to ensuring and maximizing information quality through existing policies, systems and programs. The Guidelines build upon our numerous existing systems and practices that address information quality to establish new policies and administrative mechanisms that respond to OMB’s guidelines. The Guidelines also identify Agency initiatives intended to provide ongoing information quality improvements.

As noted in the Guidelines, beyond information generated by EPA itself, the Agency uses and disseminates information developed through EPA contracts, grants, and cooperative and interagency agreements, as well as information submitted to EPA as part of a requirement under a statute, regulation, permit, order or other mandate. EPA generally has considerable influence over the quality² of this information *at the time the information is generated*. As summarized below in Section 2 (and more broadly referenced in Appendix 1), existing quality controls that EPA applies are based on EPA’s Quality System, Peer Review Policy, and other agency-wide and program-specific policies, as well as specific provisions in contracts, grants, agreements, and regulations.

On the other hand, the Agency also receives information that is voluntarily submitted to EPA by external sources (“third parties”) in hopes of influencing Agency actions. EPA may also gather information for its own use from external sources in order to develop policies, regulatory decisions, and other actions. These two types of information from external sources are the focus of the assessment factors and considerations described in this document. Third parties may include sources such as other federal, state, tribal, local, and international agencies; national laboratories; academic and research institutions; business and industry; and public interest organizations. As discussed below in Section 3 (and more broadly illustrated in Appendix 2), this information may include scientific studies published in journal articles, testing or survey

¹ The EPA Guidelines were developed pursuant to the Office of Management and Budget’s *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* (“OMB’s guidelines,” 67 Fed. Reg. 8452, Feb. 22, 2002).

² In the EPA Guidelines, the definition of quality is consistent with the definition in OMB’s Guidelines. Quality includes objectivity, utility and integrity of disseminated information. “Objectivity” focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. “Integrity” refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. “Utility” refers to the usefulness of the information to the intended users.

data, such as environmental monitoring or laboratory test results, and analytic studies, such as those that model environmental conditions or that assess risks to public health. EPA's quality system does not apply at the time this information is generated. However, EPA does apply applicable quality controls *at the time EPA uses or disseminates this information*. EPA needs to consider the quality of the information relative to the Agency's intended use of the information, especially when using the information in decision making and various Agency actions. EPA is also responsible for how such information may be presented to the public in Agency products to ensure objective and clear presentation of third party information.

The purpose of this document is to describe sets of "assessment factors" that illustrate the types of considerations that EPA takes into account when evaluating the quality and relevance of information that is voluntarily submitted or that we obtain from external sources in support of various Agency actions. We note, however, that this document is not a regulation, and therefore it is not intended to create legal rights or impose legally binding requirements or obligations on EPA or the public. EPA's goal in developing this document is to make these factors broadly known to those who generate information. Our objective is to enhance the extent to which important information quality considerations are built into the design, methods, performance, models, analyses and documentation *at the time the information is generated as well as disseminated*. It is our expectation that publication of these assessment factors will maximize our ability to appropriately use and disseminate information from external sources in support of Agency actions.

This document identifies five general categories of assessment factors that are broadly applicable to most types of information (see Box). Taken together, these categories also address the transparency of information, which is an important aspect of information quality³. Within this framework, Section 4 below presents various illustrative sets of assessment factors that are specifically formulated to address different types of information. The foundation for these illustrative factors originates in Agency guidelines, practices, and other procedures that comprise the EPA information and quality systems. The

Categories of general assessment factors broadly used to evaluate the quality and relevance of information from external sources

- *Soundness*: The extent to which the procedures, measures, methods, or models employed to generate the information are reasonable for and consistent with the intended application and are scientifically/technically appropriate.
- *Applicability and Utility*: The extent to which the information is applicable and appropriate for the Agency's intended use.
- *Clarity and Completeness*: The degree of clarity and completeness with which the data, assumptions, methods, quality controls, and analyses employed to generate the information are documented.
- *Uncertainty and Variability*: The extent to which the variability and uncertainty in the information or in the procedures, measures, methods, or models are evaluated and characterized.
- *Evaluation and Review*: The extent of independent application, replication, evaluation, validation, and peer review of the information or of the procedures, measures, methods, or models employed to generate the information.

³Although not defined in the OMB Guidelines, "transparency" generally refers to the clarity and completeness with which data, assumptions, and methods of analysis are documented, such that replication is possible if information is sufficiently transparent.

factors are intended to be sufficiently flexible so that they can be meaningfully applied to the broad range of information that supports Agency actions and to the varying degrees of significance and urgency of Agency actions.

Consistent with the non-regulatory nature of this document, EPA retains discretion to consider and use factors and approaches on a case-by-case basis, as appropriate, that may differ from the illustrative assessment factors presented here. When EPA is evaluating the quality of particular information, interested parties are free to raise questions and objections about these factors and the appropriateness of using them in that particular situation, and EPA will take any such questions or concerns into account in our evaluation of the information in that situation.

2. EPA's Existing Information Quality Systems, Practices, and Guidelines

The EPA Guidelines provide some examples of the existing systems and practices that are already in place to address the quality, objectivity, utility, and integrity of information disseminated by EPA. In general, these systems apply to the use and dissemination of information by EPA from any source, including information submitted to EPA or obtained by EPA from external sources. Two key examples of such over-arching systems are the EPA Quality System and Peer Review Policy. The EPA Quality System helps ensure that EPA organizations maximize the quality of environmental information, including information disseminated by the Agency. A graded approach is used to establish quality criteria that are appropriate for the intended use of the information and the resources available. The Quality System is documented in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and the "EPA Quality Manual for Environmental Programs" (EPA Order 5360 A1)⁴. The EPA Peer Review Policy provides that major scientifically and technically based work products (including scientific, engineering, economic, or statistical documents) related to Agency actions and regulatory decisions should be peer-reviewed. This policy is detailed in *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency* and the related *Peer Review Handbook*⁵ provides guidance for implementing the policy.

Other systems and practices that help to address the quality, objectivity, utility, and integrity of information used and disseminated by the Agency include the Agency's Action Development Process, the Information Resources Management Manual, and the Risk Characterization Policy and Handbook. These and other related reference materials are included in Appendix 1.

⁴"Policy and Program Requirements for the Mandatory Agency-wide Quality System (May 5, 2000)" and "EPA Quality Manual for Environmental Programs (2000)," <http://www.epa.gov/quality>.

⁵ "Peer Review and Peer Involvement at the U.S. EPA (June 7, 1994)" and "The Science Policy Council Peer Review Handbook (December 2000)," <http://www.epa.gov/osp/spc>.

3. Types of Information Submitted or Obtained from External Sources

A large amount of information is submitted to or obtained by EPA from external sources every year. Most of this information is submitted to or obtained by EPA with the intent of expanding or improving the information available to EPA as a basis for its policies, regulatory decisions, and other actions. This information may consist of data and/or analytic results. These information products may range from brief descriptions of chemical uses or markets to detailed and rigorously conducted scientific studies which quantify a chemical's toxicity or characterize population exposures and risks to a specific substance. Various types of analytic studies that exemplify the range of information received from external sources include the following: environmental modeling studies, engineering data and analyses, exposure monitoring and assessments, hazard and risk assessments, economic data and analyses, and social data and assessments. Illustrative examples of various types of data and analytic studies that are submitted to or obtained by the Agency from external sources are shown in Appendix 2.

In recent years, EPA has placed greater emphasis on the management of environmental issues on a cooperative basis with stakeholders. This cooperative emphasis has greatly increased the flow of information submitted on a voluntary basis to EPA from external sources. Over time, the amount and the importance of information submitted by or obtained from external sources is likely to increase and grow in importance to EPA policy development and decision making.

4. Assessment Factors

Ideally, all information voluntarily submitted by, or that EPA obtains from, external sources would be developed and documented using the same standards, guidelines, and controls that EPA imposes on itself and on those who gather data on behalf of the Agency or in response to Agency requirements. These information quality tools include both Agency-wide and program- and discipline-specific standards, guidelines, and controls (See Appendix 1 for a representative listing of publicly available tools). Some external investigators take advantage of these tools to improve the quality and relevance of their information products, and the likelihood that the information will be used to support Agency actions.

EPA understands that there are gradations in the quality and relevance of information submitted by, or obtained from, external sources. This means that not all information needs to be at the same level of quality and relevance for it to be appropriately used and disseminated by EPA. Information that is sufficient for one Agency use, such as research planning, may be insufficient for a different Agency use, such as regulatory development. Accordingly, when EPA considers using information from external sources for a particular purpose, careful judgment is applied to evaluate the information for quality and relevance relative to the potential significance and urgency of the Agency action being developed. For instance, in the context of a given action, EPA may need to weigh the appropriateness of using information with significant, but known uncertainties to fill "data gaps," relative to using default assumptions or committing additional resources to generate more certain information.

For purposes of considering the quality and relevance of an information product, the information product is generally evaluated relative to the five categories of assessment factors that are summarized in Section 1: the *soundness* of its underlying theory or approach; its *applicability and utility* relative to its intended use; the *clarity and completeness* of its documentation; its characterization of *uncertainty and variability*; and the extent of *evaluation and review*. These categories reflect the most salient features of the EPA information quality policies and guidelines. Whether the information consists of scientific theories, computer codes for modeling environmental systems, environmental monitoring data, economic analyses, social survey or demographic data, chemical toxicity testing, environmental fate and transport predictions, or a human health risk assessment, EPA generally evaluates the information by applying these five general assessment categories to each information product.

Below are a few simple illustrative examples of applying the five general assessment factor categories to information products for a variety of information types:

Soundness: *The extent to which the procedures, measures, methods, or models employed to generate the information are reasonable for and consistent with the intended application and are scientifically/technically appropriate.*

- To what extent are the procedures, measures, methods, or models employed to develop the information reasonable and consistent with sound scientific theory or standard approaches?

- If novel or alternative theories or approaches are used, how clearly are they explained and the differences highlighted?

- Is the study design consistent with scientific or economic theory? Are the assumptions, governing equations and mathematical descriptions employed clearly justified? Is the study based on sound scientific or econometric principles?

- In the case of a survey, have the questionnaires and other survey instruments been validated (e.g., compared with direct measurement data)? Were checks for potential errors made during the interview process (e.g., using computer-assisted interviews)?

Applicability and Utility: *The extent to which the information is applicable and appropriate for the Agency's intended use.*

- How useful or applicable is the scientific or economic theory applied in the study to the Agency's intended use of the analysis?

- How relevant are the study design, outcome measures, and results to the Agency's intended use of the analysis (e.g., for a chemical hazard characterization)?

• Are the domains (e.g., duration, species, exposure) where the model or results are valid useful to the Agency's application?

• In the case of a survey, are conditions likely to have changed since the survey was completed (i.e., is the information still relevant)? Is the sampled population relevant to the Agency's current application? How well does the sample take into account sensitive subpopulations?

Clarity and Completeness: *The degree of clarity and completeness with which the data, assumptions, methods, quality controls, and analyses employed to generate the information are documented.*

• To what extent does the documentation clearly and completely describe the underlying scientific or economic theory and the analytic methods used?

• To what extent have key assumptions, parameter values, measures, domains, and limitations been described and characterized?

• To what extent are the results clearly and completely documented as a basis for comparing them to results from other similar tests?

• Is the complete data set accessible, including metadata, data-dictionaries, and embedded definitions (e.g., codes for missing values, data quality flags, and questionnaire responses)?

• In the case of a modeling exercise, have the definitions and units of model parameters been provided? To what extent have the procedures for applying the model been clearly and completely documented? How available and adequate is the information necessary to run the model computer code?

Uncertainty and Variability: *The extent to which the variability and uncertainty in the information or in the procedures, measures, methods, or models are evaluated and characterized.*

• To what extent have appropriate statistical techniques been employed to evaluate variability and uncertainty? To what extent have the model's sensitive parameters been identified and characterized?

• To what extent do the uncertainty and variability impact the conclusions that can be inferred from the data and the utility of the study?

• Were the Quality Assurance and Quality Control procedures employed documented and the results of all quality control samples reported?

• Did the study identify potential uncertainties such as those due to inherent variability in environmental and exposure-related parameters or possible measurement errors?

Evaluation and Review: *The extent of independent application, replication, evaluation, validation, and peer review of the information or of the procedures, measure, methods, or models employed to generate the information.*

• To what extent has independent application, replication, evaluation, validation, and peer review been conducted and taken into account?

• Has the procedure, method or model been used in similar, peer reviewed studies? Are the results consistent with other relevant studies?

• To what extent are the descriptions of the study or survey design clear, complete, and sufficient to allow replication of the study or survey?

• In the case of a modeling exercise, to what extent has independent evaluation and testing of the model code been performed and documented?

5. Summary

This document describes the assessment factors and considerations generally used by the Agency to evaluate the quality and relevance of the broad range of third party information submitted to or obtained by the Agency from external sources. These factors are founded in the Agency guidelines, practices and procedures that make up the EPA information and quality systems including existing program-specific quality assurance policies. However, the assessment factors are sufficiently flexible to encourage the use of external information by EPA, as appropriate for the significance and urgency of the Agency action under development, while also ensuring the quality of the information products that EPA disseminates. Consistent with the EPA Guidelines to ensure and maximize information quality, this assessment factors document is considered to be a living document and may be revised periodically to reflect changes in EPA's approach for ensuring that data and information provided by external sources or obtained by EPA from external sources is of sufficient quality and transparency to support its intended use by the Agency.

Appendix 1

REPRESENTATIVE REFERENCE MATERIALS

Overview: Appendix 1 is intended to provide examples of reference materials the EPA published and/or relies upon to assist reviewers when assessing the quality of scientific and technical information. This Appendix is not an all inclusive list and the Agency recognizes other reference materials can be utilized.

Laboratory Practices and Protocols

Good Laboratory Practice Standards, Code of Federal Regulations, Protection of Environment (U.S. Environmental Protection Agency), Title 40, Part 160.

Good Laboratory Practice for Nonclinical Laboratory Studies, Code of Federal Regulations, Food and Drugs (U.S. Food and Drug Administration), Title 21, Part 58.

Good Automated Laboratory Practices - EPA Directive 2185:

http://www.epa.gov/irmpoli8/irm_galp/

U.S. Environmental Protection Agency (USEPA) *OPPTS Harmonized Test Guidelines*, Guidelines Series 810, 830, 835, 840, 850, 860, 870, 875, 880, and 885, Office of Prevention, Pesticides, and Toxic Substances. http://www.epa.gov/OPPTS_Harmonized/

Organisation for Economic Cooperation and Development (OECD) *OECD Guidelines for the Testing of Chemicals*, <http://www.oecd.org/EN/home/0,,EN-home-524-nodirectorate-no-no-no-8,00.html>

U. S. Environmental Protection Agency (USEPA) (2002) *SW-846 Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*, Office of Solid Waste, July 2002. <http://www.epa.gov/epaoswer/hazwaste/test/main.htm#Table>

Quality Systems and Assurance

For most Quality System documents, go to http://www.epa.gov/quality/qa_docs.html#EPArqts

U.S. Environmental Protection Agency (USEPA) (2000) *Policy and Program Specifications for the Mandatory Agency-wide Quality System*, EPA Order 5360.1 A2, U.S. Environmental Protection Agency, May 2000.

- 258 U.S. Environmental Protection Agency (2000) *EPA Quality Manual for Environmental*
259 *Programs*, EPA Manual 5360 A1, May 2000. [http://www.epa.gov/QUALITY/qs-](http://www.epa.gov/QUALITY/qs-docs/5360.pdf)
260 [docs/5360.pdf](http://www.epa.gov/QUALITY/qs-docs/5360.pdf)
- 261 U.S. Environmental Protection Agency (USEPA) (2000) *Guidance for the Data Quality*
262 *Objectives Process (G-4)*, U.S. Environmental Protection Agency, EPA/600/R-96/055,
263 August 2000.
- 264 U.S. Environmental Protection Agency (USEPA) (2000) *Guidance on Technical Audits and*
265 *Related Assessments (G-7)*, U.S. Environmental Protection Agency, EPA/600/R-99/080,
266 January 2000.
- 267 U.S. Environmental Protection Agency (USEPA) (2000) *Guidance for Data Quality Assessment:*
268 *Practical Methods for Data Analysis (G-9)*, QA00 Version, EPA/600/R-96/084, July
269 2000.
- 270 U.S. Environmental Protection Agency (USEPA) (2001) *EPA Requirements for Quality*
271 *Management Plans (QA/R-2)*, EPA/240/B-01/002, March 2001.
- 272 U.S. Environmental Protection Agency (USEPA) (2001) *EPA Requirements for QA Project*
273 *Plans (QA/R-5)*, EPA/240/B-01/003, March 2001.
- 274 U.S. Environmental Protection Agency (USEPA) (2001) *Guidance for Preparing Standard*
275 *Operating Procedures (G-6)*, EPA/240/B-01/004, March 2001.
- 276 U.S. Environmental Protection Agency (USEPA) (1995) *QA/QC Guidance for Sampling and*
277 *Analysis of Sediments, Water, and Tissues for Dredged Material valuations, Chemical*
278 *Evaluations*, Office of Water, EPA/823/B-95-001, 1995.
- 279 U.S. Environmental Protection Agency (USEPA) (1998) *Quality Assurance Guidance for*
280 *Conducting Brownfields Site Assessments*, Office of Solid Waste and Emergency
281 Response, EPA 540-R-98-038, September 1998.
282 http://www.clu_in.com/download/char/brwnfdqa.pdf
- 283 U.S. Environmental Protection Agency (USEPA) (1998) *OSWER PBMS Implementation Plan*.
284 Office of Solid Waste and Emergency Response, October 1998.
285 <http://www.epa.gov/epaoswer/hazwaste/test/pdfs/pbms.pdf>
- 286 U.S. Environmental Protection Agency (USEPA) (2001) *Ensuring Data Quality with Field-*
287 *based Analytical Methods (Chapter III)*. December 2001.
288 http://www.epa.gov/superfund/programs/dfa/download/guidance/chap_3.pdf

- 289 U. S. Environmental Protection Agency (USEPA) (1994) *Quality Assurance Handbook for Air*
290 *Pollution Measurement Systems, Volume I - A Field Guide to Environmental Quality*
291 *Assurance*, Office of Air and Radiation, EPA 600R-94/038a, April 1994.
292 <http://www.epa.gov/ttn/amtic/>
- 293 U. S. Environmental Protection Agency (USEPA) (1994) *Quality Assurance Handbook for Air*
294 *Pollution Measurement Systems, Volume V - Precipitation Measurement Systems*
295 *(Interim Edition)*, Office of Air and Radiation, EPA 600R-94/038e, April 1994.
296 <http://www.epa.gov/ttn/amtic/>
- 297 U. S. Environmental Protection Agency (USEPA) (1995) *Quality Assurance Handbook for Air*
298 *Pollution Measurement Systems, Volume IV - Meteorological Measurements*, Office of
299 Air and Radiation, EPA 600R-94/038d, March 1995. <http://www.epa.gov/ttn/amtic/>
- 300 U. S. Environmental Protection Agency (USEPA) (1998) *Quality Assurance Handbook for Air*
301 *Pollution Measurement Systems, Volume 2- Ambient Air Quality Monitoring Program*
302 *Quality System Development*, Office of Air and Radiation, EPA-454/R-98-004, August
303 1998. <http://www.epa.gov/ttn/amtic/>
- 304 U. S. Environmental Protection Agency (USEPA) (1998) *Quality Assurance Handbook for Air*
305 *Pollution Measurement Systems, Volume III - Stationary Source Specific Methods*, Office
306 of Air and Radiation, EPA 600R-94/038c, September 1998.
307 <http://www.epa.gov/ttn/amtic/>
- 308 U. S. Environmental Protection Agency (USEPA) *Ambient Air Monitoring Reference and*
309 *Equivalent Methods*, 40 CFR Part 53.
- 310 U. S. Environmental Protection Agency (USEPA) *Ambient Air Quality Surveillance*, 40 CFR
311 Part 58.
- 312 **Peer Review**
- 313 U.S. Environmental Protection Agency (USEPA) (2000) *Science Policy Council Handbook:*
314 *Peer Review, 2nd Edition*, EPA 100-B00-001, Washington, DC: U.S. Environmental
315 Protection Agency, December 2000.

Models***References related to modeling in general***

U.S. Environmental Protection Agency (USEPA) Council on Regulatory Environmental Modeling, <http://www.epa.gov/osp/crem.htm>.

U.S. Environmental Protection Agency (USEPA) (1989) *Resolution on Use of Mathematical Models by EPA for Regulatory Assessment and Decision Making*, SAB-EEC-89-012.

American Society for Testing and Materials (1992) *Standard Practice for Evaluating Environmental Fate Models of Chemicals*, ASTM Standard 978-92.
<http://www.astm.org/cgi-bin/SoftCart.exe/index.shtml?E+mystore>

U.S. Environmental Protection Agency (USEPA) (1994) *Report of the Agency Task Force on Environmental Regulatory Modeling – Guidance, Support Needs, Draft Criteria and Charter*, EPA 500-R-94-001.

U.S. Environmental Protection Agency (USEPA) (1994) *Model Validation for Predictive Exposure Assessments*, <http://www.epa.gov/osp/crem/documents/ModelValProt.pdf>.

U.S. Environmental Protection Agency (USEPA) (1994) *Agency Guidance for Conducting External Peer Review of Environmental Regulatory Models*, EPA 100-B-94-001.

U.S. Environmental Protection Agency (USEPA) (1999) *White Paper on the Nature and Scope of Issues on Adoption of Model Use Acceptability Guidance* (Science Policy Council)

U.S. Environmental Protection Agency (USEPA) (2001), *Final Report on the “U.S. EPA Models Evaluation and Peer Review Workshop,”* March 30, 2001.

References for Specific Model Applications

U.S. Environmental Protection Agency (USEPA) (1987) *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models*, EPA/600/8-87/042.

U.S. Environmental Protection Agency (USEPA) (1988) *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-Water Models* EPA/600/8-88/075.

U.S. Environmental Protection Agency (USEPA) (1989) *Predicting Subsurface Contaminant Transport and Transformation: Considerations for Model Selection and Field Validation* (Weaver 1989), EPA/600/2-89/045.

344 U.S. Environmental Protection Agency (USEPA) (1993) *Selection Criteria for Mathematical*
345 *Models Used in Exposure Assessments: Atmospheric Dispersion Models*, EPA/600/8-
346 91/038.

347 U.S. Environmental Protection Agency (USEPA) (1994) *A Technical Guide to Ground-Water*
348 *Selection at Sites Contaminated with Radioactive Substances*, EPA 402-R-94-012.

349 U.S. Environmental Protection Agency (USEPA) (1997) *Compendium of Tools for Watershed*
350 *Assessment and TMDL Development*, EPA 841-B-97-006.

351 U.S. Environmental Protection Agency (USEPA) (1999) Appendix W of 40 CFR Part 51:
352 *Guideline on Air Quality Models*. <http://www.epa.gov/scram001/tt25.htm#guidance>

353 **Health Assessments**

354 U.S. Environmental Protection Agency (USEPA) (1986) *Guidelines for Carcinogen Risk*
355 *Assessment*, Federal Register 51: 33992-34003, 24 September 1986; also EPA
356 Publication No. EPA/600/8-87/045, August 1987.

357 U.S. Environmental Protection Agency (USEPA) (1999) *Draft Guidelines for Carcinogen Risk*
358 *Assessment*, EPA Publication No. NCEA-F-0644, July 1999,
359 http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf.

360 U.S. Environmental Protection Agency (USEPA) (1986) *Guidelines for Mutagenicity Risk*
361 *Assessment*, Federal Register 51: 34006-34012, 24 September 1986; also EPA
362 Publication No. EPA/600/8-87/045, August 1987.

363 U.S. Environmental Protection Agency (USEPA) (1986) *Guidelines for the Health Risk*
364 *Assessment of Chemical Mixtures*, Federal Register 51: 34014-34025, 24 September
365 1986; also EPA Publication No. EPA/600/8-87/045, August 1987.

366 U.S. Environmental Protection Agency (USEPA) (2000) *Supplemental Guidance for Conducting*
367 *Health Risk Assessment of Chemical Mixtures*, EPA Publication No. EPA/630/R-00/002,
368 August 2000.

369 U.S. Environmental Protection Agency (USEPA) (1991) *Guidelines for Developmental Toxicity*
370 *Risk Assessment*, Federal Register 56: 63798-63826, 5 December 1991.

371 U.S. Environmental Protection Agency (USEPA) (1996) *Guidelines for Reproductive Toxicity*
372 *Risk Assessment; Notice*, Federal Register 61: 56274-56322, 31 October 1996.

- 373 U.S. Environmental Protection Agency (USEPA) (1998) *Assessment of Thyroid Follicular Cell*
374 *Tumors*, EPA Publication No. EPA/630/R-97/002, March 1998.
- 375 U.S. Environmental Protection Agency (USEPA) (1998) *Guidelines for Neurotoxicity Risk*
376 *Assessment; Notice*, Federal Register 60: 26926-26954, 14 May 1998.
- 377 U.S. Environmental Protection Agency (USEPA) (1997) *Guiding Principles for Monte Carlo*
378 *Analysis* (contains: Policy for Use of Probabilistic Analysis in Risk Assessment at the
379 U.S. Environmental Protection Agency), EPA Publication No. EPA/630/R-97/001,
380 March 1997.
- 381 U.S. Environmental Protection Agency (USEPA) (1999) High Production Volume (HPV)
382 Challenge Program: Determining the Adequacy of Existing Data.
383 <http://www.epa.gov/opptintr/chemrtk/datadfin.htm>
- 384 **Ecological Assessments**
- 385 U.S. Environmental Protection Agency (USEPA) (1998) *Guidelines for Ecological Risk*
386 *Assessment*, Federal Register 63: 26846-26924, 14 May 1998; also EPA Publication No.
387 EPA/630/R-95/002F, April 1998.
- 388 U.S. Environmental Protection Agency (USEPA) (1993) *Wildlife Exposure Factors Handbook*,
389 EPA Publication No. EPA/600/R-93/187, December 1993.
- 390 Stephan et al. (1985) *Guidelines for Deriving Numerical National Water Quality Criteria for the*
391 *Protection of Aquatic Organisms and Their Uses*, U.S. Environmental Protection Agency
392 (USEPA), Office of Research and Development.
- 393 U.S. Environmental Protection Agency (USEPA) (1997) *Incidence and Severity of Sediment*
394 *Contamination in the Surface Waters of the United States. Vol. 1. National Sediment*
395 *Quality Survey*, EPA/823/R-97-006, 1997.
- 396 U.S. Environmental Protection Agency (USEPA) (2000) *Ambient Water Quality Criteria*
397 *Recommendations. Information Supporting the Development of State and Tribal Nutrient*
398 *Criteria. Lakes and Reservoirs in Nutrient Ecoregion XI*, Office of Water, EPA 822-B-
399 00-012, Dec. 2000, Appendix C, pp 20 and Appendix A, pp A1-A6)
400 <http://www.epa.gov/waterscience/criteria/nutrient/ecoregions/lakes/>
- 401 U.S. Environmental Protection Agency (USEPA) (2000) National Guidance for Assessing
402 Chemical Contaminants Data for use in Fish Advisories. Vol. 1 Fish Sampling and
403 Analysis - Third Edition. Office of Water, EPA/823-B-00-007, November 2000.
404 <http://www.epa.gov/waterscience/fish/guidance.html>

U.S. Environmental Protection Agency (USEPA) (2000) National Guidance for Assessing Chemical Contaminants Data for use in Fish Advisories. Vol. 2 Risk Assessment and Fish Consumption - Third Edition. Office of Water, EPA/823-B-00-008, November 2000. <http://www.epa.gov/waterscience/fish/guidance.html>

Economic Assessments

U.S. Environmental Protection Agency (USEPA) (2000) *Guidelines for Preparing Economic Analyses*, EPA 240-R-00-003, Washington, DC: Office of the Administrator, U.S. Environmental Protection Agency, September 2000. <http://yosemite.epa.gov/ee/epa/eed.nsf/pages/guidelines>

U.S. Environmental Protection Agency (USEPA) (2000) *Handbook for Non-Cancer Health Effects Valuation*, Report prepared by the Non-Cancer Health Effects Valuation Subcommittee of the EPA Social Science Discussion Group, EPA Science Policy Council, December 2000. <http://epa.gov/osp/spc/Homeqs.htm>

U.S. Environmental Protection Agency (USEPA) (1999) *Cost of Illness Handbook*, Report prepared for the Office of Pollution Prevention and Toxics by Abt Associates, Inc. Washington, DC, 1999. <http://www.epa.gov/oppt/coi/>

U.S. Environmental Protection Agency (USEPA) (1999) *OAQPS Economic Analysis Resource Document*, Report prepared by the Innovative Strategies and Economics Group, Office of Air Quality Planning and Standards, April 1999. <http://www.epa.gov/ttn/ecas/analguid.html>

U.S. Environmental Protection Agency (USEPA) (2001) *A Framework for the Economic Assessment of Ecological Benefits*, Washington, DC: U.S. Environmental Protection Agency, February 2001. <http://www.epa.gov/osp/spc/feab3.pdf>

Exposure and Social Science Assessments

U.S. Environmental Protection Agency (USEPA) (1983) *Survey management handbook. Volume I: Guidelines for planning and managing a statistical survey*, U. S. Environmental Protection Agency, Office of Policy, Planning, and Evaluation, Washington, DC. EPA-230/12-84-002, November 1983. 105 pp. + appendices. National Technical Information Service, PB85-187672, Springfield, VA.

U.S. Environmental Protection Agency (USEPA) (1984) *Survey management handbook. Volume II: Overseeing the technical progress of a survey contract*, U. S. Environmental Protection Agency, Office of Policy, Planning, and Evaluation, Washington, DC. EPA-

437 230/12-84-002, December 1984. 168 pp. National Technical Information Service PB85-
438 187680, Springfield, VA.

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Appendix 2

EXAMPLES OF THIRD PARTY INFORMATION SUBMITTED TO OR OBTAINED BY EPA

Overview: Third party information includes any information voluntarily submitted to EPA or obtained by EPA that is not paid for nor provided to EPA under a statutory or regulatory obligation. Third party information is prepared independently by parties external to EPA including, academia, scientific journals, database searches from internet, other federal/region/tribal/state/local agencies, international organizations, foreign government agencies, individual companies, commercial enterprises, industry trade groups and advocacy groups. The following are examples of the types of information EPA receives or obtains from third parties for use in exposure assessments, modeling, risk assessments, economic analysis and environmental monitoring.

Exposure Assessments and Monitoring

Information collected for estimating the frequency and magnitude of human and ecological exposures to environmental pollutants.

Exposure Assessments submitted to EPA in conjunction with the High Production Volume (HPV) Challenge Program. These assessments supplement basic, screening-level hazard and environmental fate data voluntarily submitted to EPA by chemical manufacturers that are sponsoring their chemicals produced in quantities greater the 1,000,000 lb/yr under the Program.

Survey Data on the Reductions of Mercury in Waste

Drinking water monitoring data used to establish the exposure from potable water used for the Relative Source Contribution applied in determining an Maximum Contaminant Level Goal (MCLG)

Sediment chemistry, sediment toxicity, and tissue residue data for use in the National Sediment Inventory Report to Congress.

National Beach Health Survey data. (e.g. water quality standards, beach monitoring procedure, beach notification procedure; name of beach, number of swimmers, season length, beach location, potential pollution sources; type of advisories and closings issued, number issued, when issued, duration, location, reason, cause.)

Data from fish advisory programs (e.g., fish tissue residue data) to determine environmental effects.

- 523 Information on services provided for hazardous waste site cleanup
- 524 Information on technology use at contaminated sites.
- 525 Information on innovative technology demonstration projects for cleanup activities.
- 526 Groundwater monitoring data, ground and surface water monitoring information.
- 527 Split sample analyses of record samples for hazardous waste listing determinations.
- 528 Data on chemical releases (leachate volume, pH, constituent concentrations, etc.) from land fills,
529 and remediation of those releases.
- 530 Effluent data for vessel discharges used for regarding impact of pollution from offshore oil and
531 gas.
- 532 **Modeling**
- 533 Scientific theories, mathematical models, computational algorithms, and computer codes for the
534 fate/transport of and human exposures to chemicals in the environment or the metabolism
535 (pharmacokinetics) of chemicals in humans and animals.
- 536 Compiled, computed, and measured values or probability distributions for pollutant source
537 release data (e.g., stack emissions, surface water effluent), environmental data/parameters
538 (e.g., land use, soil properties, aquifer properties, meteorological data), human and
539 ecological exposure factors (e.g., ingestion rates, inhalation rates, time-activity patterns),
540 or metabolic parameters (e.g., uptake, elimination, and transfer coefficients in different
541 physiologic compartments or organs).
- 542 Planting dates and pesticide application dates, application rates, and reports for water modeling
543 purposes.
- 544 Economic models and data for developing cost-benefit analyses of environmental rules and
545 regulations.
- 546 **Risk Assessments (Human and Health and Ecological)**
- 547 Screening-level hazard and environmental fate data voluntarily submitted to EPA by chemical
548 manufacturers that are sponsoring their chemicals produced in quantities greater the
549 1,000,000 lb/yr under the High Production Volume (HPV) Program.

- 550 Risk assessments for use in the Organization for Economic Cooperation and Development
551 (OECD) program known as Screening Information Data Set (SIDS) program.
- 552 Toxicity data used in completing or creating a minimum data base for deriving aquatic life
553 criteria.
- 554 Toxicity and microbiological data for use in aquatic life and human health ambient criteria and
555 in Health Advisories and MCLGs for drinking water.
- 556 Databases searched for identifying primary sources of data available on toxicity, fate and
557 transport of chemicals (e.g., TOXLINE, MEDLINE, CANCERLINE, RTECS,
558 GENETOX, TSCATS, and HSDB).
- 559 Hazard and dose-response information for revisions of Integrated Risk Information System
560 (IRIS) assessments.
- 561 Biomonitoring data used to support exposure and risk assessments.
- 562 Pesticide poisoning incident data used to indicate adverse effects of registered pesticides.
- 563 Wildlife incidents of death, disease data, groundwater chemical contamination incidents data
564 used in risk assessments.
- 565 **Economic Analysis**
- 566 Price data for analytical services (e.g. TCLP tests).
- 567 Capital and annual O&M costs (e.g. sludge dewatering cost data).
- 568 Truck transportation costs for pick-up and hauling solid and hazardous wastes.
- 569 Information on manufacturing processing and use of chemicals including economics data.
- 570 Annual "Economic Report of the President" (statistical appendices on prices, employment,
571 GDP).
- 572 Information on populations, demographics, economic, location, business patterns, plant capacity,
573 etc.
- 574 Employment cost trends, employment cost index, occupational employment statistics.
- 575 Economic models and data, environmental impacts data.

576 Surveys (to provide documentation of potential regulatory costs, etc.) used in support of
577 rulemakings and to supplement Reports to Congress.

578 Economic information for assessing health effects, technology, costs and benefits, and
579 occurrence.

580 **Social Assessments**

581 Databases of information about demographics and residential/housing characteristics of the
582 population.

583 Census or large-scale demographic surveys (including age, gender, race/ethnic group).

584 Information on housing characteristics (e.g., sources for the pollutants of concern, and
585 description of the indoor spaces where most exposures occur) for human exposure
586 modeling.

587 Information on consumer product usage to estimate the frequency of exposures to certain
588 household chemicals such as cleaning and disinfection products, paints, and pesticides.

589 Surveys on human and ecological exposure factors (e.g., ingestion rates, inhalation rates, time-
590 activity patterns).

591 Food consumption data is used to estimate pesticide residue exposure from the diet, and to
592 estimate fish and shellfish consumption rates and per capita water ingestion.

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